AUG 10 2000

AUSTENAL

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K001815

Zirconium Oxide for the DCS Precident CAD/CAM System
510(k) Premarket Notification Summary

The Zirconium Oxide for the DCS CAD/CAM System is furnished in a block form that is designed for use as the feed stock for the DCS Precident CAD/CAM System to produce copings and/or substrates for fixed all ceramic dental restorations; i.e. porcelain fused to zirconium oxide restorations. This is subtantially equivalent in concept to the Nobel Biocare Procera System that CAD/CAM machines substructure from blocks of aluminum oxide.

Zirconium Oxide has been in use successfully as part of the DCS Precident System in Europe.

The safety and efficacy of Zirconium Oxide is well established. This material complies with the requirements of ASTM F 1893-98 Standard Specification for the High Purity Dense Yttria Tetragonal Zirconium Oxide for Surgical Implant Applications. The suitability of Zirconium Oxide for the substructure of dental restorations has also been demonstrated in the dental industry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2000

Mr. Ronald Dudek
Director of Technical Resources
Austenal, Incorporated
4101 West 51st Street
Chicago, Illinois 60632-4287

Re: K001815
Trade Name: DC Zirkon
Regulatory Class: II
Product Code: EIH
Dated: June 7, 2000
Received: June 15, 2000

Dear Mr. Dudek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division Of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001815

Device Name: DC-ZIRKON

Indications For Use:

The indications for use for DC-ZIRKON is as a substructure for porcelain fused ceramic fixed dental restorations; namely crowns and bridges. Substructures of DC-ZIRKON are machined using the DCS Precident CAD/CAM System.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Gerald W Shipley for MSR
(Division Sign Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001815